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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/939,885	08/27/2001	Susan Niemiec	J&J-2047	5256

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EXAMINER

KISHORE, GOLLAMUDI S

ART UNIT	PAPER NUMBER
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1615

DATE MAILED: 12/12/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/939,885

Applicant(s)

Niemiec

Examiner

Gollamudi Kishore

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE three MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Oct 1, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above, claim(s) 14-23 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-13 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____ 6) ☐ Other:

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DETAILED ACTION

1. Applicant's election with traverse of Group I in Paper No. 6 is acknowledged. The traversal is on the ground(s) that there is no burden on the examiner. This is not found persuasive because according to MPEP section 808.02 (which comes under 803 (b) serious burden), the examiner has to establish one of subsections A, B or C and examiner has already established separate classification (subsection A)..

The requirement is still deemed proper and is therefore made FINAL.

Claims included in the prosecution are 1-13.

Claim Rejections - 35 USC § 112

2. Claims 1-13 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

According to claim 1, the lipid vesicles encapsulate a conditioning polymer. According to claim 3, the conditioning polymer is polyoxyethylene ether. However, the dependent claims 9-12 recite polyoxyethelene ether as a single chain lipid. Clarification is requested as to whether this compound is a conditioning polymer or a single chain lipid forming the lipid vesicle. Furthermore, claims 9-12 recite additional components and these claims depend from claims 5-8 which recite only a dual chain lipid. The examiner therefore, suggests reciting the expression, 'further containing' in these claims.

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Claim Rejections - 35 USC § 102

3. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

4. Claims 1, 4-5, 8 and 13 are rejected under 35 U.S.C. 102(b) as being anticipated by Delrieu (5,962,015).

Delrieu discloses liposome formulations containing lecithin (dual chain lipid) and a polymer, quaternized polysaccharide (note the abstract, col. 2, line 55 through col. 5, line 53; Examples and claims). The liposomes also include, the moisturizer, hyaluronic acid (col. 7, line 34). The formulations are for cleansing, beautifying and conditioning or protecting the body surface (note col. 7, lines 59-62).

5. Claims 1, 4, 5 and 8 are rejected under 35 U.S.C. 102(b) as being anticipated by Product brochure, BROOKOSOMES (August, 1989).

This brochure shows that phospholipid liposomes containing hyaluronate is commercially available (note pages 6 and 7). The compositions are used as cosmetic compositions and meant for skin.

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

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6. Claims 1, 3, 5, 7, and 13 are rejected under 35 U.S.C. 102(b) or (a) as being anticipated by Yoshika (5,846,458).

Yoshika discloses lecithin liposomes containing polyoxyethylene ethers (note the abstract, col. 8, lines 48-52 and Example 1).

7. Claims 1, 3, 5, 7, 9, 11 and 13 are rejected under 35 U.S.C. 102(b) or (a) as being anticipated by WO 98/46208.

WO discloses compositions which contain liposomes. The liposomes are made of glyceryl dilaurate (dual chain lipid), cholesterol, a cationic lipid which is fatty acid salt of quaternary amine and polyoxyethylene -10-stearyl ether (conditioning polymer) (note the abstract, page 9, lines 10-24; pages 22-23). The compositions also include DNA which could be construed as a conditioning polymer.

8. Claims 1, 5, 9 and 13 are rejected under 35 U.S.C. 102(b) or (a) as being anticipated by WO 96/31194.

WO 96 discloses skin care compositions containing non-phospholipid liposomes. The compositions containing glyceryl distearate (dual chain lipid), glyceryl monostearate (single-chain lipid), cholesterol, polysorbate 80 (detergent) and steareth-10 (conditioning polymer). The compositions also include cyclomethicone, conditioning polymer (note pages 23-24, 32-33).

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Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 2 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over

Delrieu (5,962,015) or Brookasomes both cited above, or Hart (5,328,628) in view of Burke (5,562,912) or vice versa (Burke in view of Delrieu or Brookasomes or Hart).

As pointed out above, Delrieu discloses liposome formulations containing lecithin (dual chain lipid) and a polymer, quaternized polysaccharide (note the abstract, col. 2, line 55 through col. 5, line 53; Examples and claims). The liposomes also include hyaluronic acid (col. 7, line 34). The formulations are for cleansing, beautifying and conditioning or protecting the body surface (note col. 7, lines 59-62).

As also pointed out above, Brookasome brochure shows that phospholipid liposomes containing hyaluronate is commercially available (note pages 6 and 7). The compositions are used as cosmetic compositions and meant for skin.

Hart teaches shower compositions containing liposomes. The liposomes are made from either phospholipids or non-phospholipids. The compositions further contain a surfactant (detergent) (note the abstract, columns 5-13 and Examples).

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What is lacking in Delrieu, Brookasomes or Hart is the inclusion of polyvinylpyrrolidone in the formulations.

Burke while disclosing skin cleanser compositions teaches that polyvinylpyrrolidone when included in the skin cleanser compositions, improves the foam character, after feel and rinsability (note the abstract and col. 3, lines 33-35).

The inclusion of polyvinylpyrrolidone in the liposome compositions taught by Delrieu, Brookasomes or Hart would have been obvious to one of ordinary skill in the art since Burke teaches that this compound when included in the skin compositions, improves the foam character, after feel and rinsability. Alternately the use of liposomes in the compositions of Burke would have been obvious to one of ordinary skill in the art because Brookasomes teaches that in their liposomal form, cosmetic agents exhibit better stability, penetration and efficacy a lower usage levels (page 3, top two lines) and because both Delrieu and Hart teach that liposomes are carriers for active agents in skin cosmetics preparations.

11. Claims 2, 6 and 10 are rejected under 35 U.S.C. 103(a) as being unpatentable over WO 96/31194 in view of Burke (5,562,912), both cited above, or vice versa (Burke in view of WO 96/31194).

As pointed out above, WO 96 discloses skin care compositions containing non-phospholipid liposomes (niosomes). The compositions containing glyceryl distearate (dual chain lipid), glyceryl monostearate (single-chain lipid), cholesterol, polysorbate 80

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(detergent) and steareth-10 (conditioning polymer). The compositions also include cyclomethicone, conditioning polymer (note pages 23-24, 32-33). Besides niosomes, WO also teaches lecithin (dual chain lipid) containing liposomes. What is lacking in WO is the teaching of the inclusion of polyvinylpyrrolidone.

As discussed above, Burke while disclosing skin cleanser compositions teaches that polyvinylpyrrolidone when included in the skin cleanser compositions, improves the foam character, after feel and rinsability (note the abstract and col. 3, lines 33-35).

The inclusion of polyvinylpyrrolidone in the liposome compositions taught by WO would have been obvious to one of ordinary skill in the art since Burke teaches that this compound when included in the skin compositions, improves the foam character, after feel and rinsability. Alternately the use of liposomes in the compositions of Burke would have been obvious to one of ordinary skill in the art, with the expectation of obtaining similar results, because WO shows that polymers can be encapsulated in skin care compositions.

12. Claims 2, 6, 10 and 12 are rejected under 35 U.S.C. 103(a) as being unpatentable over Brookasomes or Delrieu cited above, in view of WO 96/31194 or vice versa.

As pointed out above, Delrieu discloses liposome formulations containing lecithin (dual chain lipid) and a polymer, quaternized polysaccharide (note the abstract, col. 2, line 55 through col. 5, line 53; Examples and claims). The liposomes also include, the moisturizer, hyaluronic acid (col. 7, line 34). The formulations are for cleansing, beautifying, conditioning and protecting the body surface.

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This brochure shows that phospholipid liposomes containing hyaluronate is commercially available (note pages 6 and 7). The compositions are used as cosmetic compositions and meant for skin.

What is lacking in Brookasomes or Delrieu is the teaching of the use of niosomes (containing claimed glycerol mono and diesters) instead of lecithin.

As discussed above, WO 96 discloses skin care compositions containing non-phospholipid liposomes (niosomes). The compositions containing glyceryl distearate (dual chain lipid), glyceryl monostearate (single-chain lipid), cholesterol, polysorbate 80 (detergent) and steareth-10 (conditioning polymer). The compositions also include cyclomethicone, conditioning polymer (note pages 23-24, 32-33). Besides niosomes, WO also discloses lecithin (dual chain lipid) containing liposomes; however, WO teaches that phospholipids are labile and expensive to purify or synthesize and that the manufacture of phospholipid liposome is difficult and costly to scale up. Therefore, WO suggests the use of above mentioned niosomes containing the glycerylestere (note page 12, lines 5-14).

It would have been obvious to one of ordinary skill in the art to use niosomes of WO for encapsulating the hyaluronate taught by Brookosomes or Delrieu because of the disadvantages of lecithin liposomes taught by Brookasomes or Delrieu.

Alternately, to encapsulate hyaluronate in WO 96 would have been obvious to one of ordinary skill in the art since Brookasomes shows the routine encapsulation of hyaluronate in liposomes and Delrieu teaches that hyaluronate is a moisturizer.

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13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to *G.S. Kishore* whose telephone number is (703) 308-2440.

The examiner can normally be reached on Monday-Thursday from 6:30 A.M. to 4:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, T.K. Page, can be reached on (703)308-2927. The fax phone number for this Group is (703)305-3592.

Communications via Internet e-mail regarding this application, other than those under 35 U.S.C. 132 or which otherwise require a signature, may be used by the applicant and should be addressed to [thurman.page@uspto.gov].

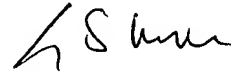
All Internet e-mail communications will be made of record in the application file. PTO employees do not engage in Internet communications where there exists a possibility that sensitive information could be identified or exchanged unless the record includes a properly signed express waiver of the confidentiality requirements of 35 U.S.C. 122. This is more clearly set forth in the Interim Internet Usage Policy published in the Official Gazette of the Patent and Trademark on February 25, 1997 at 1195 OG 89.

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Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-1235.



Gollamudi S. Kishore, Ph. D

Primary Examiner

Group 1600

gsk

December 11, 2002